Remarks

Claims 1-38 were previously pending in the subject application. By this Amendment, claims 1, 4, 7, 8, 16-18, 21, 22, 26, and 31 have been amended, and claims 29, 30, 32-36, and 38 have been cancelled. The undersigned avers that no new matter is introduced by this amendment. Entry and consideration of the amendments presented herein is respectfully requested. Upon entry of this Amendment, claims 1-29 and 37 will be before the Examiner for consideration. Favorable consideration of the pending claims is respectfully requested.

Claims 1-3, 9-11, 15, 28, 31, 37, and 38 have been rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,282,953 (Ayer *et al.*). Applicants respectfully traverse these grounds of rejection because Ayer *et al.* does not teach or suggest their claimed methods.

Applicants have invented unique methods for monitoring patient compliance in taking a medication. As noted above, claims 1 and 31 have been amended to clarify the claimed invention, namely methods for monitoring a patient's compliance in taking a medication by volitional action at specified times. Furthermore, claim 38 has been canceled, thus rendering moot the rejection of this claim. Applicants respectfully submit that Ayer *et al.* provides no teaching or suggestion of monitoring patient compliance in taking a medication.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

> Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSIH Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSIH, supra; Kalman [v. Kimberly-Clarke*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Ayer *et al.* does not disclose methods for monitoring patient compliance in taking a medication. Rather, Ayer *et al.* addresses a different issue by providing methods for monitoring the delivery rate and performance of medications automatically delivered by delivery devices internally

implanted by the caregiver. Because the medication has been administered by the caregiver, the caregiver has no motivation or need to monitor patient compliance. In contrast, the present invention monitors patient compliance in taking medications that are external to the patient's body and that are required to be taken by the patient at specified times, through the patient's own actions. Thus, under the applicable statutory and case law, Ayer *et al.* does not anticipate Applicants' claims. Therefore, reconsideration and withdrawal of the rejection under 35 USC §102(e) is respectfully requested.

Claims 32-36 have been rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,237,397 (Shinar *et al.*). As noted above, claims 32-36 have been cancelled by this Amendment. Thus, the rejection of claims 32-36 is moot in view of their cancellation. Accordingly, reconsideration and withdrawal of this rejection under 35 U.S.C. §102(e) is respectfully requested.

Claims 6 and 12-14 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Ayer *et al.* in view of U.S. Patent No. 5,167,972 (Greenberg *et al.*). Applicants respectfully traverse these grounds for rejection and hereby incorporate by reference the comments asserted above regarding Ayer *et al.*

As noted above, nothing in Ayer *et al.* would have led the skilled artisan to the advantageous methods currently claimed by Applicants. Greenberg *et al.* merely discloses the use of flavorings, including cinnamaldehydes, citrus oils, and fruit essences, in drugs to improve taste. The Office Action indicates that it would have been obvious to combine the methods of monitoring drug delivery rate of internally implanted delivery devices as taught by Ayer *et al.* and the methods of improving drug taste as taught by Greenberg *et al.*

A finding of obviousness is proper only when the prior art contains a suggestion or teaching of the claimed invention. Here, it is only Applicants' disclosure that provides such a teaching, and Applicants' disclosure cannot be used to reconstruct the prior art for a rejection under 35 U.S.C §103. This was specifically recognized by the CCPA in *In re Spommoble*, 56 CCPA 823, 160 USPQ 237, 243 (1969):

> The Court must be ever alert not to read obviousness into an invention on the basis of the applicant's own statements; that is we must review the prior art without reading into that art appellant's teachings. *In re Murray*, 46 CCPA 905, 268 F.2d 226, 112 USPQ 364 (1959); *In re Sprock*, 49 CCPA 1039, 301 F.2d 686, 133 USPQ 360 (1962). The issue, then, is whether the teachings of the prior art would, in and of themselves and without the benefits of appellant's disclosure, make the invention as a

whole, obvious. *In re Leonor*, 55 CCPA 1198, 395 F.2d 801, 158 USPQ 20 (1968). (Emphasis in original)

The mere fact that the purported prior art could have been modified or applied in a manner to yield Applicants' invention would not have made the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Moreover, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art . . . ." *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). As noted above, the claims have been amended to clarify the claimed invention, namely methods for monitoring a patient's compliance in taking a medication by volitional action at specified times. Ayer *et al.* fails to teach or suggest methods for monitoring patient compliance in taking medication. Greenberg *et al.* merely pertains to including specific flavorings to drugs, and does not teach or disclose methods for monitoring patient compliance in taking medication. Thus, the skilled artisan would not have found in Greenberg *et al.* any remedy to the defects previously noted regarding Ayer *et al.*

Both Ayer *et al.* and Greenberg *et al.* concern unrelated processes. One of ordinary skill in the art would have had no motivation to modify the cited teachings without the guidance of Applicants' disclosure. Without such motivation, no *prima facie* case of obviousness is set forth. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 4, 5, 7, 8, 16, 17, 21-25, 29, and 30 have been rejected under 35 U.S.C. §103(a) as obvious over Ayer *et al.* in view of Shinar *et al.*, WO 99/12471 (Katzman *et al.*), U.S. Patent No. 5,771,890 (Tamada), and U.S. Patent No. 5,042,501 (Kenny *et al.*). Applicants respectfully traverse, and hereby incorporate by reference the comments asserted above regarding Ayer *et al.*

As discussed above, in order to establish a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claim limitations recited in the claimed invention. The claims have been amended to clarify the claimed invention, namely methods for monitoring a patient's compliance in taking a medication by volitional action at specified times. Ayer *et al.* in view of either Shinar *et al.*, Katzman *et al.*, Tamada, or Kenny *et al.* fail to teach, suggest, or provide the motivation for methods to monitor patient compliance in taking medications.

Shinar *et al.* provides specialized coatings that improve the detection of volatile organic compounds with mass sensors. Shinar *et al.* does not disclose the use of such coatings in methods for monitoring patient compliance. Therefore, the skilled artisan would have had no reason to look to Shinar *et al.* for guidance in developing methods for monitoring patient compliance.

Katzman *et al.* discloses the use of isotope-labeled compounds to perform diagnostic tests to monitor the medical condition of a patient. Katzman *et al.* does not teach, either expressly or impliedly, the monitoring of patient compliance in taking a medication by analyzing the concentration of specific markers administered with the medication. Thus, Katzman *et al.* fails to remedy, or even address, the defects previously noted in either Shinar *et al.* or Ayer *et al.*

Tamada discloses methods of sampling substances that are secreted from the skin in the presence of an electrical current. As noted above, claims 29 and 30 have been canceled rendering moot the rejection of these claims. Thus, Tamada does not disclose or even suggest methods for monitoring patient compliance in taking medications by analyzing detectable markers in patient breath.

Kenny *et al.* discloses apparatuses and methods for analyzing exhaled breath condensates, which are different from gaseous exhaled breath, as claimed in the subject application. Thus, the skilled artisan would not have found in Kenny *et al.* any remedy to the defects previously noted in either Shinar *et al.*, Katzman *et al.*, Tamada, or Ayer *et al.*

As noted above, the mere fact that the teachings of a prior art reference could have been modified or applied in a manner to yield Applicants' invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. The cited references provide no indication as to why the skilled artisan, having knowledge of the references, would have been motivated to modify their teachings to arrive at the subject invention. Further, Applicants respectfully submit that one of ordinary skill in the art would not have been motivated to modify the cited references to derive methods for monitoring patient compliance in the absence of the guidance provided by Applicants' disclosure. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

Finally, claims 18-20, 26, and 27 have been rejected under 35 U.S.C. §103(a) as obvious over Ayer *et al.* in view of U.S. Patent No. 5,776,784 (Kell). Applicants respectfully traverse, and hereby incorporate by reference the comments asserted above in regard to Ayer *et al.*

The shortcomings of Ayer *et al.* are not cured by Kell. Kell discloses the administration of medication and a marker, methadone, which is to be measured in a patient's urine sample to assess patient compliance in taking the medication. The marker disclosed by Kell must be metabolized and excreted in urine and is not detectable in exhaled breath. There is no motivation to combine Ayer *et al.* with Kell. Thus, Applicants respectfully submit that no case of *prima facie* obviousness has been set forth. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims under 35 U.S.C. §103.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,

Jeff Lloyd
Patent Attorney
Registration No. 35,589
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: Saliwanchik, Lloyd & Saliwanchik
A Professional Association
2421 NW 41st Street, Suite A-1
Gainesville, FL 32606-6669

JL/sp

Attachments: Petition and Fee for Extension of Time
Marked-Up Version of Amended Claims

S:\SH-RESP\UF\246XC1 resp.doc/DNB/mv

Docket No. UF-246XC1
Serial No. 09/708,789

Marked-Up Version of Amended Claims

Claim 1 (amended):

A method of determining patient compliance in taking a medication, comprising

providing to the patient a combination of a medication [with]and a detectable marker, the combination to be taken by the patient as a result of the patient's own actions,

obtaining a sample of the patient's gaseous exhaled breath; and

[subsequently]analyzing the sample of the patient's breath to confirm the presence or absence of said marker [and thus the taking of said medication]in the patient's breath as an indication of patient compliance or non-compliance in taking the medication; wherein the medication is to be taken by volitional patient action at specified times.

Claim 4 (amended):

The method of claim 3 wherein the sample of the patient's breath is analyzed to confirm the presence of said marker by sensor technology selected from semiconductor gas sensor technology, conductive polymer gas sensor technology, or surface acoustic wave gas sensor technology.

Claim 7 (amended):

The method of claim 1 wherein the sample of the patient's breath is analyzed to confirm the presence of said marker by a spectrophotometer.

Claim 8 (amended):

The method of claim 1 wherein the sample of the patient's breath is analyzed to confirm the presence of said marker by mass spectrometer.

Claim 16 (amended):

The method of claim 1 further comprising the step of recording data resulting from analysis of the sample of the patient's breath.

Claim 17 (amended):

The method of claim 1 further comprising the step of transmitting data resulting from the analysis of the sample of the patient's breath.

Claim 18 (amended):

The method of claim 1 where the analysis of the sample of the patient's breath includes comparing the marker sensed in the sample of the patient's breath with a predetermined signature profile of a specific marker.

Claim 21 (amended):

The method of claim 1 further comprising the step of capturing the sample of the patient's breath in a vessel prior to analysis.

Claim 22 (amended):

The method of claim 1 further comprising the step of dehumidifying the sample of the patient's breath prior to analysis.

Claim 26 (amended):

The method of claim 1 wherein the data resulting from analysis of the sample of the patient's breath includes marker concentration and, thus, medication concentration.

Claim 31 (amended):

A method of producing medication which is detectable as an indication of [for] patient compliance in taking the medication comprising the steps of:

identifying a [detectable] marker substance detectable in gaseous exhaled breath, and

producing a medication combined with said detectable marker substance, said medication to be taken by volitional patient action at specified times [by the patient] whereby subsequent analysis of the patient's breath will confirm the presence of said marker substance and thus the patient's compliance in taking [of]said medication.